

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

In the specification, paragraphs have been amended on page 1. Claims 4, 7, 12 – 21 and 25 – 35 are requested to be cancelled. Claims 1, 3, 8, 10, 11, and 22 are currently being amended. After amending the claims as set forth above, claims 1 – 3, 5, 6, 8 – 11, and 22 – 24 are now pending in this application.

I. Title

On page 2 of the office action the examiner suggested a new title because the present title of the application is “no longer descriptive.” Applicants thank the examiner for his kind suggestion for a new title, viz., “Pyrrolo-[2,3-b]-pyridin-2-ones.” Applicants note, however, that the suggested title is too narrow in that it only covers one type of compound, specifically a compound that has a pyrrole ring attached to the pyridin-2-one core. The claims are not limited to compounds that contain a pyrrole ring attached to the pyridin-2-one core. The claims, even as amended, are directed to compounds that contain, *inter alia*, imidazole and thiophene rings attached to the pyridine-2-one core. In short, applicants do not wish to amend the title of the application, as it seems to be more descriptive than “Pyrrolo-[2,3-b]-pyridin-2-ones.”

II. Priority

Applicants have amended the specification such that it contains a specific reference to prior applications.

III. Rejections of claims under 35 U.S.C. § 112, second paragraph

A. Claims 1 – 3, 5 – 10, 22 – 24

Claims 1 – 3, 5 – 10, 22 – 24 stand rejected under 35 U.S.C. § 112, second paragraph because the term “comprising” and the term “optionally substituted” are allegedly indefinite. While not acquiescing to the examiner’s position but simply in an effort to

expedite the prosecution of this application, applicants have amended claim 1 to incorporate the subject matter of original claim 7. In so doing, applicants have removed the terms “comprising” and “optionally substituted” from claim 1. Consequently, the rejection of claims 1 – 3, 5 – 10, and 22 – 24 under 35 U.S.C. § 112, second paragraph is now moot. Reconsideration and withdrawal of the rejection is respectfully requested.

B. Claim 3

Claim 3 stands rejected under 35 U.S.C. § 112, second paragraph because the term “and derivatives thereof” is allegedly indefinite. While not acquiescing to the examiner’s position but simply in an effort to expedite the prosecution of this application, applicants have amended claim 3 such that it no longer recites “and derivatives thereof.” Consequently, the rejection of claim 3 under 35 U.S.C. § 112, second paragraph is now moot. Reconsideration and withdrawal of the rejection is respectfully requested.

C. Claims 22 – 24

Claims 22 – 24 stand rejected under 35 U.S.C. § 112, second paragraph because the claims refer to Formula I and that formula is not recited in those claims. Applicants have made claim 22 dependent upon claim 1, thus overcoming the rejection of claims 22 – 24 under 35 U.S.C. § 112, second paragraph moot. Reconsideration and withdrawal of the rejection is respectfully requested.

IV. Rejection of claims under 35 U.S.C. § 112, first paragraph

A. Claims 1 – 3, 5 – 11, and 22 – 24

Claims 1 – 3, 5 – 11 and 22 – 24 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for making salts of the claimed compounds, it is allegedly not enabling for making solvates, clathrates, or prodrugs of the claimed compounds. While not acquiescing to the examiner’s position, and simply in an effort to expedite the prosecution of this application, applicants have amended claims 1, 11, 22, and

32 such they no longer recite “clathrates, or prodrugs.” To the extent that this rejection may apply to claims 1 – 3, 5 – 11, 22 – 24 as amended, Applicants respectfully traverse the rejection.

Applicants understand the Examiner to accept that the recited pharmaceutically acceptable salts are fully enabled while solvates are not. Drawing a distinction between the two, however, makes no chemical sense. The formation of solvates, as with making salts, is a common procedure in the pharmaceutical arts. Solvates often are encountered in the crystallization or isolation of pharmaceutical compounds and their related salts. Those who are skilled in this art, a “B.S. chemist” in the Examiner’s words (Office Action at page 8), know this to be so and would not be obliged to undertake a research program, as the Examiner apparently suggests, to find out how to accomplish this routine feat. In fact, the Patent Office and its reviewing courts specifically sanction the *exclusion* from the specification any teaching of what is well known in the art. *See MPEP § 2164.01 (Version 8, revision 2, May 2004).* That is precisely what Applicants have done.

In support of this rejection, the Examiner alleged that the “numerous examples presented all failed to produce a solvate” and therefore posited the notion that if “solvates of these compounds actually exist . . . they would have formed.” Office Action at page 7. This misunderstands the enablement requirement. First, nowhere does the specification teach that the examples failed to produce solvates. In fact, the conditions under which the exemplified compounds were synthesized are conducive to the formation of solvates and there is no evidence to suggest that solvates were *not* formed.

Second, the enablement requirement and chemical sense neither support nor hold Applicants to the proposed standard that a compound *must* form a solvate if it *can* form a solvate. It is well-settled law that the enablement requirement presents the question of whether the experimentation needed to practice the invention is undue or unreasonable. *Id.* As discussed above, making solvates is a routine practice in the pharmaceutical arts, and therefore hardly introduces the element of unpredictability underlying the Examiner’s analysis. Consequently, and in Applicants’ favor, the Examiner relied upon *Morton International*. This case affirmed the non-enablement of claims directed to exotic organotin

compounds, particularly in light of the patentee's Ph.D. NMR specialist putting on contested spectral evidence of the compounds.

By contrast to *Morton International*, making solvates falls well within the purview of a "B.S. chemist" following time-honored and art-recognized procedures. Applicants are thus under no obligation to "show *that* solvates can be made," Office Action at page 7 (emphasis added), but rather teach that solvates *can* be made. For the reasons above, Applicants meet this requirement. Accordingly, the claims are enabled and the Examiner is respectfully requested to reconsider and withdraw this ground for rejection.

V. Conclusion

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

Date Oct. 15, 2004

By Steve M. Reid Reg. No. 54,343

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5300
Facsimile: (202) 672-5399

foc / Matthew E. Mulkeen
Attorney for Applicants
Registration No. 44,250

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.